

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CONFLUENT SURGICAL, INC., )  
INTEGRA LIFESCIENCES )  
CORPORATION, and INTEGRA )  
LIFESCIENCES SALES LLC, )

Plaintiffs, )

v. )

Civil Action No. 17-688-LPS-CJB

HYPERBRANCH MEDICAL )  
TECHNOLOGY, INC., )

Defendant. )

**REPORT AND RECOMMENDATION**

1. In this patent infringement action filed by Plaintiffs Confluent Surgical, Inc., Integra LifeSciences Corporation and Integra LifeSciences Sales LLC (collectively, “Plaintiffs”) against Defendant HyperBranch Medical Technology, Inc. (“Defendant”), pending is Defendant’s motion dismiss a portion of the currently-operative Amended Complaint (“Motion”), filed pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 18) More specifically, Defendant moves to dismiss: (1) Counts III and V of the Amended Complaint, which allege export infringement pursuant to 35 U.S.C. §§ 271(f)(1) & (2) (“Section 271(f)”; and (2) allegations in Counts I, II and IV of the Amended Complaint regarding infringement of United States Patent No. 9,101,946 (“the ‘946 patent”) by the Defendant’s AutoSpray Extended Tip (ET) Dural Sealant product. (D.I. 19 at 1-2, 16) The Motion has been referred to the Court for resolution, (D.I. 8), was fully briefed on September 15, 2017, (D.I. 21), and was argued on October 23, 2017.

2. With regard to Defendant’s argument that Plaintiffs have not sufficiently pleaded

plausible claims of export infringement under Section 271(f), the Court agrees.<sup>1</sup> Sections 271(f)(1) and (f)(2) each require, *inter alia*, that Defendant supply or cause to be supplied “component(s)” of a patented invention that are “uncombined in whole or in part[,]” all while either: (1) (as to Section 271(f)(1)) actively inducing the combination of such components outside of the United States in an infringing manner; or (2) (as to Section 271(f)(2)) intending that such component will be combined outside the United States in an infringing manner. 35 U.S.C. § 271(f). In Counts III and V, Plaintiffs clearly rely on the asserted presence of unnamed “first and second components of the system [of Defendant’s Adherus AutoSpray Dural Sealant product]” that are supplied by Defendant along with “components of the applicator”; Defendant is then alleged to provide instructions on how to combine these components together in an infringing manner overseas. (D.I. 14 at ¶ 39; *see also id.* at ¶ 53) But in the absence of Plaintiffs providing any hint in the Amended Complaint as to what those first and second components are said to be, the Court could not discern whether it is plausible that the accused products at issue

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<sup>1</sup> The standard of review here is the familiar two-part analysis applicable to motions made pursuant to Rule 12(b)(6). First, the court separates the factual and legal elements of a claim, accepting “all of the complaint’s well-pleaded facts as true, but [disregarding] any legal conclusions.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). Second, the court determines “whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A plausible claim does more than merely allege entitlement to relief; it must also demonstrate the basis for that “entitlement with its facts.” *Fowler*, 578 F.3d at 211. Thus, a claimant’s “obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In assessing the plausibility of a claim, the court must “construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

are, in fact, supplied from the United States as separate components.<sup>2</sup> In their answering brief, (D.I. 20 at 9), Plaintiffs suggest that here they were referring to certain vials (and their contents) that are supplied from the United States in conjunction with the applicator for the accused products. To the extent this is so, it is not made clear by the contents of the Amended Complaint (or the attached exhibits thereto). Plaintiffs must further amend to make this clear.<sup>3</sup>

3. With regard to Defendant's argument that Plaintiffs have not sufficiently pleaded plausible claims of infringement as to the '946 patent, the Court disagrees. Defendant contends that Plaintiffs have failed to allege facts sufficient to plausibly show that every limitation of at least one claim of the '946 patent is contained in its AutoSpray Extended Tip (ET) Dural Sealant product. (D.I. 19 at 16-17) The claims of that patent recite a spray assembly that comprises, *inter alia*, an elongated portion including an inner shaft and an outer sleeve, with the "the inner shaft defining a first lumen . . . , a second lumen . . . , and a third lumen configured for fluid communication with the source of pressurized air[.]" (*See, e.g.*, D.I. 14, ex. F, col. 6:27-40) In support of its argument, Defendant points to an exhibit to the Amended Complaint wherein Plaintiffs provide more information about their infringement allegations with regard to the '946 patent. (*Id.*, ex. P) Defendant argues that these allegations assert that the "third lumen" in the accused product at issue is found in an "outer sleeve" of the product, not an "inner shaft," and

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<sup>2</sup> Put differently, Plaintiffs' bald reference to additional "first and second components" is not much different in effect than if Plaintiffs had simply tracked the language of the statute (i.e., had simply alleged that an accused product contained "component[s]" and nothing more) in making their allegations of export infringement. Plaintiffs have to do more than merely track the statutory language—they have to allege *facts* that go beyond a formulaic recitation of the elements of their cause of action.

<sup>3</sup> If Plaintiffs do so, the Court would not perceive their allegations in Count III and V to otherwise be deficient in any other manner suggested by Defendant in its briefs.

that this renders any allegation of infringement implausible. (D.I. 19 at 17-18; D.I. 21 at 9-10) But Plaintiffs correctly respond that, to the extent that the Court can discern from the pleading a plausible allegation of infringement of this limitation—even one that may not prevail ultimately after claim construction—they have met their burden. (D.I. 20 at 12-13)<sup>4</sup> And here (supplemented by an explanation from Plaintiffs’ counsel at oral argument), the Court can see how the record indicates that there are plausible readings of the limitation at issue that could allow for a finding of infringement. That is, the claims might be read: (1) to require only that the inner shaft need to “defin[e]” the third lumen (not that the third lumen be contained in the inner shaft), and that this could be accomplished by way of the interrelationship between the inner shaft and the outer sleeve of the product; or (2) that the structure of the limitation is such (in light of certain commas contained therein) that the inner shaft need not actually define the third lumen at all. (*See* D.I. 14, ex. P at 147)<sup>5</sup>

4. For the foregoing reasons, the Court recommends that the Motion be GRANTED-IN-PART, in that the Motion be granted with regard to Counts III and V and otherwise be denied. As there is not suggestion that it would be futile, unduly prejudicial or otherwise inappropriate to

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<sup>4</sup> *See also D&M Holdings Inc. v. Sonos, Inc.*, Civil Action No. 16-141-RGA, 2017 WL 1395603, at \*11 (D. Del. Apr. 18, 2017) (denying a motion to dismiss allegations of direct infringement where the defendant asserted that plaintiffs did not plausibly allege infringement of several limitations of the asserted claims, because the motion to dismiss stage is not the appropriate time for claim construction and because plaintiffs’ complaint included plausible allegations addressing each limitation of the asserted claims); *cf. Pragmatus AV, LLC v. Yahoo! Inc.*, Civil Action No. 11-902-LPS-CJB, 2012 WL 6044793, at \*8 (D. Del. Nov. 13, 2012) (explaining that typically, “[t]o engage in the claim construction process upon review of a motion to dismiss would be to go beyond the scope of a court’s traditional gatekeeping role in reviewing such a motion”).

<sup>5</sup> Here the Court refers to the ECF page number associated with the exhibit at issue.

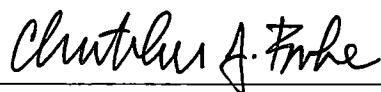
do so, the Court recommends that (to the extent its recommendation of dismissal is affirmed by the District Court) the District Court permit Plaintiffs to file a Second Amended Complaint further setting forth their allegations as to Counts III and V. It also recommends that, to the extent Defendant later wishes to file a motion seeking dismissal of that Second Amended Complaint: (1) such a Motion be limited to challenging the sufficiency of Counts III and V with the exception that (2) to the extent that the new allegations regarding Counts III and V call into question the sufficiency of Plaintiffs' allegations of direct infringement under 35 U.S.C. ¶ 271(a) in Count I, (D.I. 14 at ¶ 25), that Defendant also then be permitted to challenge the sufficiency of the allegations in Count I as well.<sup>6</sup>

5. This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006). The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>.

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<sup>6</sup> In light of this, it may behoove Plaintiffs, in filing a Second Amended Complaint, to provide additional facts in Count I articulating how (in light of their allegations as to export infringement in Counts III and V), Plaintiffs can plausibly assert that, as to those same accused products, Defendant makes, uses, offers to sell or sells the (fully assembled) products in the United States.

Dated: October 25, 2017

Handwritten signature of Christopher J. Burke in black ink.

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Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE